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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,732	12/20/2004	Robert M Lorence	18025-PCTUS	3190

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,732	LORENCE, ROBERT M	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-12,17,21-23,26-32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 6,9-12, 17, 21-23, 26-32, 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 05/03/07. Claim 1 has been amended. Claims 7-8, 10-11, 13-16, 18-20, 24-25, 33 and 35-71 have been canceled. Claims 1-6, 9, 12, 17, 21-23, 26-32 and 34 are pending before the examiner. Claims 31-32 were withdrawn from the consideration. Claims 1-6, 9, 12, 17, 21-23, 26-30 and 34 in the scope of NDV are considered before the examiner.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double-patenting rejection is appropriate where the conflict claims are not identical but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 14U F.3d 1428, 46 USPQZd 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQZd 2010 (Fed. either anticipated by, 1993); In re Longi, F.2d 887, 225 US/Q 645 (Fed. Cir. 1985). The following rejections are all obvious double patenting rejections based on the broadly claimed methods cited in each of the copending applications with same inventor. Although the conflicting claims are not identical, they are not patentably distinct from each other.

4. Claims 1-5, 6, 26, 27, 29, 30, and 34 are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-12 of the copending Application No. 10,547,654 in view of Lorence R. (WO 94/25627A1).

5. In the response, applicants traverse the rejection and submit that the claimed method is drawn to initialize at least two desensitization dose followed by one more escalated does, for total of at least three sequential increasing dose levels, wherein the mount of the virus in the second and any subsequent desensitization dose is greater then amount of the virus in the preceding desensitization dose, and the mount of virus in each of the escalated doses is higher the amount of virus in each of the desensitization dose. The double patenting rejection is not directed to a regiment that utilizes two-step desensitization prior to the escalated doses.

6. Applicants' argument has been respectfully considered, however, it is not found persuasive. Regarding the at least two desensitization dose followed by one more escalated does, wherein the doses are at least 1X108 PFU per square meter or at up to $3.0X10^9$ PFU or up to 3.3 or $6.7X10^8$ or up to $5X10^{10}$ PFU. The conflict claims cite that the method comprising at least one cycle of one or more desensitization doses followed by one or more escalated doses for up to $7X10^8$PFU or $2X10^8$ PFU, indicating the method comprises two or more times of desensitization

followed by two or more times of escalated dosages. While the precise doses in the conflict claims are not identical as the rejected claims drafted, it is still considered within the range as claims drafted. A person with an ordinary skill in the art would have been obviously for selecting a dosage range for treating cancer/tumor effectively as Dr. Lorence R, taught in (WO 94/25627A1): "Effective dosage and schedules for administering the virus may be determined empirically, and making such determinations is within the skill in the art (Please see page 11)." Therefore, absence unexpected result to the contrary, the claimed method is still considered as prima facie obvious absence unexpected results. The rejection is maintained.

8. Regarding the argument that any subsequent desensitization dose is greater then amount of the virus in the preceding desensitization dose, and the mount of virus in each of the escalated doses are higher the amount of virus in each of the desensitization dose, such limitations are not in the rejected claims.

9. Claims 1-5, 6, 9, 12, 17, 21-29, 30, 34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 14-15, 18-19 of copending Application No. 10,548,057 in view of Lorence R. (WO 94/25627A1). Upon reconsidering the pending claims and the conflict claims, the rejection has been modified.

10. In the response, applicants traverse the rejection and submit the same argument cited above.

11. Applicants' argument has been respectfully considered, however, it is not found persuasive. Regarding the at least one cycle of sequentially one or more initial doses from up to $7.0X10^{8}$ or $2\ X10^{8}$PFU per square meter of patients surface area in any ten minutes or selected from $1.8X10^{10}$ to $4.8\ X10^{10}$ PFU per square meter followed by one more escalated doses ranges from $2.4\ X\ 10^{10}$to $1.2.0X10^{11}$PFU per square meter pf patient surface area. Moreover, the conflict claims cite the initial one or more doses is desensitization doses, and the amount of the virus in each escalated dose is higher than the amount of the virus in each of desensitization does. Therefore, the method cited in the conflict claims comprises two or more times of desensitization followed by two or more times of escalated dosages. While the precise doses in the conflict claims are not identical as the rejected claims drafted, it is still within the range that

meets the limitation as claims drafted. A person with an ordinary skill in the art would have been obviously for selecting a proper dosage range for treating cancer/tumor effectively as Dr. Lorence R, taught in (WO 94/25627A1) that "Effective dosage and schedules for administering the virus may be determined empirically, and making such determinations is within the skill in the art (Please see page 11)." Absence unexpected result to the contrary, the claimed method is still considered as prima facie obvious absence unexpected results. Hence, the rejection is maintained.

11. Claims 1-5, 29 and 34 are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13, 16-17 of copending Application No. 10,700,143 in view of Lorence R. (WO 94/25627A1).

12. In the response, applicants traverse the rejection and submit that the claimed method is drawn to initialize at least two desensitization dose followed by one more escalated does, for total of at least three sequential increasing dose levels, wherein the mount of the virus in the second and any subsequent desensitization dose is greater then amount of the virus in the preceding desensitization dose, and the mount of virus in each of the escalated doses is higher the amount of virus in each of the desensitization dose. The double patenting rejections are not directed to a regiment that utilizes two step desensitization prior to the escalated does.

13. Applicants' argument has been respectfully considered, however, it is not found persuasive. Because the claims 13, 16-17 of copending Application No. 10,700, 143 are also directed to use at least one cycle of more than one desensitization dose followed by one or more escalated doses, wherein the escalated doses is higher than the desensitization dose. Although doses and time frame for the administration are not particular identically cited in the claims, a person with an ordinary skill in the art would have been obviously to use an appropriate range of the dosages to effectively kill the tumor cells. Because Lorence R teaches in the secondary reference WO94/25627A1 that "Effective dosage and schedules for administering the virus may be determined empirically, and making such determinations is within the skill in the art (Please see page 11)." Absence unexpected result to the contrary, the claimed method is still considered

as prima facie obvious absence unexpected results. Hence, The double patenting rejection is maintained.

14. Regarding the argument that any subsequent desensitization dose is greater then amount of the virus in the preceding desensitization dose, and the mount of virus in each of the escalated doses are higher the amount of virus in each of the desensitization dose, such limitations are not in the rejected claims.

15. Claims 1-4 and 34 are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 118, 119, 120, 133, 149, 150 of copending Application No. 10,167,652 n view of Lorence R. (WO 94/25627A1).

16. Regarding ODP rejection of claims 1-5 and 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,056,689 in view of Lorence R (WO 94/25627A1), Applicant's arguments, filed on may 03, 2007, with respect to reference the ODP rejection of said claims have been fully considered and are persuasive. The ODP rejection of 1-5 and 34 has been withdrawn.

17. Claims 1-5 and 34 are still provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 157, 166, 174, 197-200, 201, 210, 217, 230, 231, 232 of copending Application No. 09,985,809 in view of Lorence R. (WO 94/25627A1).

17. In the response, applicants traverse the rejection and submit that the same argument cited above.

18. Applicants' argument has been respectfully considered, however, it is not found persuasive. Because the claimed method still read on obvious version for claims 157, 166, 174, 197-200, 201, 210, 217, 230, 231, 232 of copending Application No. 09,985,809 in view of Lorence R. (WO 94/25627A1). Since claims 174, 197-200, 201, 210, 217, 230, 231, 232 of copending Application No. 09,985,809 are also directed to use more than one doses of treatment, while it cites the first dose is the desensitization dose, the following more than one or two doses, which is cited to be higher than the initial desensitization does could also serve as desensitization

purpose. Although precise doses and administration schedule are not particular identically each from other, a person with an ordinary skill in the art would have been obviously to use an appropriate range of the dosages to effectively kill the tumor cells. Because Lorence R teaches in the secondary reference WO94/25627A1 that "Effective dosage and schedules for administering the virus may be determined empirically, and making such determinations is within the skill in the art (Please see page 11)." Absence unexpected result to the contrary, the claimed method is still considered as prima facie obvious absence unexpected results. Hence, The double patenting rejection is maintained.

19. Regarding ODP rejection of claims 1-5 and 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,056,689 in view of Lorence R (WO 94/25627A1), Applicant's arguments, filed on may 03, 2007, with respect to reference the ODP rejection of said claims have been fully considered and are persuasive. The ODP rejection of 1-5 and 34 has been withdrawn.

Claim Rejections - 35 USC § 102/103

`The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 1-5, 6, 9, 12, 17, 21-23, 26-30, 34 are still rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lorence R (B) (WO 99/18799A1) in view of Lorence R. (A) (WO 94/25627A1).

21. Applicants traverse the rejection and submit that the claimed method is drawn to initialize at least two desensitization dose followed by one more escalated does, for total of at least three sequential increasing dose levels, wherein the mount of the virus in the second and any subsequent desensitization dose is greater then amount of the virus in the preceding desensitization dose, and the mount of virus in each of the escalated doses is higher the amount of virus in each of the desensitization dose. Whereas the cited references disclose, at most, only two-step desensitization regiment.

22. Applicants' argument has been fully considered; however, it is not found persuasive because the claimed method cited in claims 1-5, 34 in Lorence R (B) (WO 99/18799A1) is also directed to use NDV for treating a tumor with more than one doses, wherein the doses are ranged from about 3 X 10^6 to about 5 X 10^{12} PFU or from about 3 X 10^8 to about 4 X 10^{11} PFU of virus per square meter of body surface area by a systematic administration (See page 31). More importantly, Lorence R. (B) points out that an advantage of the disclosed method is that a desensitizing dose is given before a higher subsequent dose is given. For sensitization, a virus dose is from 1 X 10^8 to about 2.4 X 10^{10} PFU/m^2, which indicates the desensitization is not limited to use one dose for only one time. After sensitization, additional virus doses of 3 X 10^8 to about 4 X 10^{12} PFU/m^2 are given to the patients. The sequential doses given after the initial desensitization dose are considered to be the equivalent to the claimed sequential desensitization does and escalated doses, because the activity served by the sequential administrations of the virus is inherent regardless what it is names artificially. Moreover, the dosages disclosed in the prior art are within the ranges as claims broadly claimed. To this context, the reference anticipates the claims.

23. Or alternatively, it would have been obvious for an ordinary skilled in the art to select an optimal dose and schedule each time of NDV for treating tumor, wherein selection of appropriate

dosage range and a treatment schedule is considered within the skill in the art as evidenced by Lorence R. (WO 94,25627A1, see page 11). Because WO94/25627A1 teaches that "Effective dosage and schedules for administering the virus may be determined empirically, and making such determinations is within the skill in the art (Please see page 11)." As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

24. Claims 1-5, 6-9, 12, 17, 21-23, 26-30, 34 are still ejected under 35 U.S.C. 102(a) as anticipated by Pecora et al. (J. Clinical Oncology May 2002, Vol. 20, no. 9, pp. 2251-2266) or, in the alternative, under 35 U.S.C. 103(a) as obvious over in view of Lorence R. (WO 94/25627A1).

(The examiner apologizes that the previous office action in line 2 has a typographic error since the rejection is inadvertently typed as 102 (b). In fact, it is apparently 102 (a) rejection since the immediate paragraph cites that claims 1-12, 17, 21-23, 33, 34 are rejected under 102(a) over the reference by (J. Clinical Oncology May 2002, Vol. 20, no. 9, pp. 2251-2266)).

25. Regarding claims 1-5, 6-9, 12, 17, 21-23, 33, 34, they are still previously rejected under 35 U.S.C. 102(a) as being anticipated by Pecora et al. (J. Clinical Oncology May 2002, Vol. 20, no. 9, pp. 2251-2266).

26. Applicants traverse the rejection and submit that the claimed method is drawn to initialize at least two desensitization doses followed by one more escalated does, for total of at least three sequential increasing dose levels, wherein the mount of the virus in the second and any subsequent desensitization dose is greater then amount of the virus in the preceding desensitization dose, and the mount of virus in each of the escalated doses is higher the amount of virus in each of the desensitization dose. Whereas the cited references disclose, at most, only two-step desensitization regiment.

27. Applicants argument has been fully considered; however, it is not found persuasive because Pecoral et al. teach a method for treating tumor with a replication-competent strain of New Castle Disease virus (PV701),, wherein one of them named ' **Desinsitizing regiment"** also comprises five dosages. The first dose is given at $\underline{12X\ 10^9}$ PFU/m^2 (desensitizing dose) on the first day followed by two doses of $\underline{24\ X\ 10^9}$ PFU/m^2, two doses of 48 X 10^9 PFU/m^2, two doses

of 72 X 10^9 PFU/m^2, two doses of 96 X 10^9 PFU/m^2 or 144 X 10^9 PFU/m^2. For each patient, all three doses were administrated within 1 week and repeated every 28 days intravenueously. Another one is named as two-week regiment, it comprises more than one doses of NDV virus administrations, i.e. a first sensitizing does is 12 X 10^9 PFU/m^2 followed by five doses of 96 X 10^9 PFU/m^2, or five doses of 120 X 10^9 PFU/m^2, wherein the dose 2 was given 4 days after does 1, the patients were given three doses per week for 2 weeks followed by 1 week of treatment. Regardless whether the initial two dosages are named as an desensitization doses and the following higher dosages are named as escalated dosages, the treatment regiments meet the limitations of the claimed method. Regarding the precise dose used each time, the broad interpretation of claims 1-12, 17, 21-23, 33, 34 still read on the prior art.

28. Or alternatively, it would have been obvious for an ordinary skilled in the art to select an optimal dose and schedule each time when use NDV for treating a patient because one the NDBV had been approve to be effective and therapeutic benefit for treating a patients via its oncolytic mechanism, the effective dosage and schedules for administering the virus may be determined empirically, and making such determinations is within the skill in the art as evidenced by Lorence R. (WO 94,25627A1, see page 11). As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

29. Claims 1-5, 6-9, 12, 17, 21-23, 26-30, 34 are still rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lorence R (WO 0062735A2) in view of Lorence R. (WO 94/25627A1).

30. Applicants traverse the rejection and submit that the claimed method is drawn to initialize at least two desensitization dose followed by one more escalated does, for total of at least three sequential increasing dose levels, wherein the mount of the virus in the second and any subsequent desensitization dose is greater then amount of the virus in the preceding desensitization dose, and the mount of virus in each of the escalated doses is higher the amount of virus in each of the desensitization dose. Whereas the cited references disclose, at most, only two-step desensitization regiment.

31. Applicants' argument has been respectfully considered; however, it is not found persuasive because Lorence R. teach a method for treating a tumor in a subject uses same kind of Newcastle Disease Virus (NDV), strain PPMK107 or strain NJ Rosin (Please see entire document, e.g. Table 1 on page 22). L More importantly, Lorence teaches that in an advantage embodiment of using desensitizing dose for reducing the lethal effect and increase the therapeutic benefit (Examples 18-, 19, 28, 29). For example, using IV desensitization, the dose is from 3X 10^8 followed by 1X 10^9 PFU/m^2. 2.5X 10^9 PFU/m^2, 5X 10^9 PFU/m^2 and 1X 10^{10} PFU/m^2 respectively (Example 18). To this context, the claims 1-12, 17, 21-23, 33, 34 all within the ranges as claims broadly drafted.

32. Or alternatively, it would have been obvious for an ordinary skilled in the art to select an optimal dose and schedule each time when use NDV for treating a patient because once the NDBV had been approve to be effective and therapeutic effect can be improved by such desensitization/escalated therapeutic regiment, selection of a precise effective dosage and schedules are considered as obvious choice, because making such determinations is within the skill in the art as evidenced by Lorence R. (WO 94,25627A1, see page 11).

Claim Rejections - 35 USC § 102

31. Regarding claims 1-5 and 34 that are rejected over claim 1 of U.S. Patent No. 7,056,689 under 102 (e) or alternatively obvious under 103 in view of Lorence R (WO 94/25627A1), Applicant's arguments, filed on May 03, 2007, have been fully considered and are persuasive. The rejection has been withdrawn. Because the primary reference does not teach or suggest using a desensitization dosage followed by escalated or higher dosages.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Baoqun Li

Bao Qun Li
06/14/2007

BAOQUN LI, MD
PATENT EXAMINER